Guidance for Submission of Volunteer Monitoring Reports (Annual Volunteer Monitoring Reports and Final Volunteer Monitoring Reports) Submitted Via Email or Mail

Process

Annual volunteer monitoring reports and final volunteer monitoring reports submitted via email or mail are entered into ePermits by Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (APHIS BRS) staff on behalf of the regulated entity. This process ensures volunteer monitoring information in reports submitted via mail or email is readily available and identified by APHIS, enhances BRS' oversight of regulated field trials, and also supports recommendations in USDA Office of Inspector General Controls Over APHIS' Introduction of Genetically Engineered Organisms Audit Report 50601-0001-32.

Submission of Volunteer Monitoring Report Information

APHIS strongly encourages the electronic submission of all reports and notices via ePermits using the link under "My Reports and Notices."

Instructions for submitting reports via ePermits is located here:

BRS Reports and Notices User Guide.pdf

Other options are email or mail. If submitting using these methods, both Confidential Business Information (CBI) and CBI-deleted or non-CBI copies should be sent to:

BRS E-mail:

BRSCompliance@aphis.usda.gov

OR

BRS Mail:

Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) Regulatory Operations Program 4700 River Rd. Unit 91 Riverdale, MD 20737

Note: This is general guidance, and required information that must be reported and due dates may vary based on the specific field trial or associated Supplemental Permit Conditions. Please contact BRS via email (<u>BRSCompliance@aphis.usda.gov</u>) or phone (BRS Compliance: 301-851-3879) for assistance and guidance.

The information contained in this document is intended as guidance, and reflects APHIS' current interpretation of applicable statutes and regulations. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations. Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Conversely, following the guidelines contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations. This guidance is to be used in conjunction with the USDA-APHIS BRS User's Guide for Notification and Permits User's Guide.

Due Date of Report

All environmental releases of regulated articles under permit require the submission of a final volunteer monitoring report, preferably as an electronic file, no later than three months from the end of the volunteer monitoring period for the authorization. A volunteer monitoring report is required even if BRS authorizes all or part of a field test site to be planted back to a regulated article of the same species (e.g., a plant back under a new authorization). In cases where volunteer monitoring was not necessary, a report of "no monitoring" must be submitted with an explanation as to why monitoring did not occur.

If the volunteer monitoring period for any site in the authorization is longer than 1 year, an annual volunteer monitoring report for the site(s) must be submitted until volunteer monitoring ceases.

- 1. The first annual volunteer monitoring report must be submitted no later than 13 months after the trial site is harvested or terminated.
- 2. Subsequent annual volunteer monitoring reports must be submitted no later than the yearly anniversary date of the first annual volunteer monitoring report.
- 3. If the last annual volunteer monitoring report for a site will be the final volunteer monitoring report for the authorization, it must be submitted no later than three months from the end of the volunteer monitoring period for the authorization.

Information to be Provided

In general, the information needed to satisfy the requirements in a volunteer monitoring report (annual or final) should be arranged in a tabular, spreadsheet format. The information described below is consistent with the ePermits module that allows the web form entry or XML uploading of volunteer report information into the system. For volunteer monitoring reports, APHIS is requesting that the same information be provided.

Volunteer Monitoring Reports

An example of a volunteer monitoring report follows:

	Applicant reports these fields for all Planted Locations																	
BR Authori Num	ization	INSTITUTION	ARTICLE	State	County	Location Name	Loc Unique ID	Location Contact and Phone Number			Final or Annual Report		Monitoring Start Date		Observation Date(s)	Number of Volunteers	Actions Taken	Comments

- **1. Permit Number.** Report the permit number.
- **2. Institution.** Report the institution name.
- **3. Article.** Report the regulated article.
- **4. State.** Report the name of the State in which the planting/release occurred.
- **5. County.** Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting/release occurred.

- **6. Location Name.** Report the release site's Location name (farm level) the same as it is listed in the authorization. *Location Name is used to designate the location, such as "Green's Farm."
- 7. Location Unique ID. This is an alphanumeric code that more specifically identifies the release site of the planting/release, typically at the field level and is used, among other reasons, to link all reports for the same field location. It can be any combination of letters or numbers that you choose, but it must be unique for each release site within each authorization. If a Location Unique ID was provided for this release site in the authorization, the applicant must use the same Unique ID in the volunteer monitoring report.
- **8.** Location contact information. Provide the name and contact information for the person responsible for volunteer monitoring at this specific location.
- **9. Planting Unique ID.** If a Planting Unique ID was provided for this release site in the planting report, the applicant must use the same Planting Unique ID in the volunteer monitoring report.
- 10. Report Date. Date of report submission.
- **11. Final or Annual Volunteer Monitoring Report**. Indicate if this is the final or last submission for this authorization or if this is an annual or interim submission.
- **12. CBI information**. Use a "Yes" or "Y" if any fields within the volunteer monitoring report are CBI. If information within the report is CBI, use brackets [] to designate CBI information within the report. If CBI is involved, submit both a CBI and CBI-deleted version.
- **13. Monitoring Period Start.** Report the date when the period of monitoring began for each site (harvest/termination date of the field test site).
- **14. Monitoring Period End.** Report the date when the period of monitoring ended for each site.
- **15. Observation Date(s).** Report the date(s) when each field test site, perimeter or fallow zone, and/or area where seed or other material potentially capable of self-propagation was buried were inspected for volunteers. Dates must fall on or between the monitoring period start and end dates.

- **16. Number of Volunteers.** Report the number (e.g. 10, 100, 1000, etc.) of volunteers observed in the planted area, perimeter or fallow zone, and/or area where seed or other material potentially capable of self-propagation was buried. Include the **unit** for number of volunteers (e.g. per field, per 1 sq. ft., per acre, etc.). If more than 100 volunteers were identified, follow a sampling strategy and provide an estimate of the number.
- **17. Actions Taken.** Provide information about any actions taken, including dates, to remove or destroy volunteers.
- **18. Additional Comments.** Provide any comments or additional information relating to the observation. Such information may include information the applicant has provided in the past or desires to add to the ePermits record, and additional information that is required by BRS, as stated in the current permit conditions and associated design protocols/SOPs, to be submitted in your report. Examples include developmental stage of volunteers (seedling, vegetative, or flowering), whether volunteers are localized/clustered (for example, southeast corner of the field) or widespread, and whether all or part of a planted field test site under this permit is planted back to a regulated article of the same species (e.g., a new authorization).

If volunteers are localized/clustered, indicate areas of clustering with GPS coordinates, in decimal degrees.

If BRS has authorized all or part of a field test site planted under this authorization to be planted back to a regulated article of the same species (e.g., a new authorization) and only a part of the site was planted back: Provide the GPS coordinates, in decimal degrees, of the area not planted back for which the volunteer monitoring period of this authorization is still in effect.

Note: Multiple comments and information may be provided for each location.

19. No-Monitoring Comments. Provide no-monitoring comments when monitoring was not necessary for this release site during the timeframe of this report. Examples include if volunteer monitoring did not occur at an interval specified under the current permit, permit conditions, and associated design protocols/SOPs, cases where different volunteer monitoring requirements (e.g., reduced volunteer monitoring period) were allowed based on identified conditions or management practices (e.g., harvest before flowering), or if monitoring is complete for a site or an authorization (final VMR). Include the volunteer monitoring end date.

Note: If BRS has authorized all or part of a field test site planted under this authorization to be planted back to a regulated article of the same species (e.g., a new authorization), the planting date under the new authorization is the volunteer monitoring end date for the replanted area for the purposes of this authorization.

Note: Multiple comments and information may be provided for each location.

Annual Volunteer Monitoring Reports

Annual volunteer monitoring reports must reflect the current observations to date and must include the required information listed in #1-19 above.